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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/258,031

02/25/1999

MAARTEN HENRIK STUIVER

U-012121-2

3286

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7590

10/21/2002

LADAS & PARRY
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 10/21/2002

29

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/258,031

Applicant(s)

STUIVER ET AL.

Examiner

Richard G Hutson

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1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-53, 55, 59 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-53, 55, 59 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Prosecution Application

The request filed on 10/24/2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/258,031 is acceptable and a CPA has been established. An action on the CPA follows.

While applicants checked the box of the request for a CPA indicating that no amendment was filed with the request, applicants have brought it to the attention of the examiner that in fact a preliminary amendment was filed with the request. This amendment is in the file and therefore the previous action based on no preliminary amendment being submitted has been withdrawn.

Applicants cancellation of claims 7-10, 12-38, 42-44, 46-50, 54, 56-58 and 61-63 and the amendment of claim 51 is acknowledged.

Claims 51-53, 55, 59 and 60 are currently pending and present for examination.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on International Application PCT/EP97/04923, filed 9/4/1997, which claims the benefit of foreign applications EPO 96 202466.7, filed 9/4/1996, and EPO 97 200 831.2 filed 3/19/1997.

It is suggested that applicants amend the first line of the specification to reflect this information.

Drawings

The drawings filed on 2/25/1999 are objected to for the reasons stated on the form PTO-948 by the draftsman.

Specification

The disclosure is objected to because of the following informalities:

The specification in Figure 10 recites and compares a number of amino acid sequences, however neither Figure 10 nor the Description of Figure 10 lists a sequence identifier (i.e. SEQ ID NO) for those sequences in addition to At26, (SEQ ID NO. 71) and At27 (SEQ ID NO. 72). See M.P.E.P. 2422.02:

2422.02 The Requirement for Exclusive Conformance; Sequences Presented in Drawing Figures

37 CFR 1.821(b) requires exclusive conformance, with regard to the manner in which the nucleotide and/or amino acid sequences are presented and described, with the sequence rules for all applications that include nucleotide and amino acid sequences that fall within the definitions. This requirement is necessary to minimize any confusion that could result if more than one format for representing sequence data was employed in a given application. It is also expected that the required standard format will be more readily and widely accepted and adopted if its use is exclusive, as well as mandatory. In view of the fact that many significant sequence characteristics may only be demonstrated by a figure, the exclusive conformance requirement of this section may be relaxed for drawing figures. This is especially true in view of the fact that the representation of double stranded nucleotides is not permitted in the "Sequence Listing" and many significant nucleotide features, such as "sticky ends" and the like, will only be shown effectively by reference to a drawing figure. Further, the similarity or homology between/among sequences can only be depicted in an effective manner in a drawing figure. Similarly, drawing figures are recommended for use with amino acid sequences to depict structural features of the corresponding protein, such as finger regions and Kringle regions. The situations discussed herein are given by way of example only and

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there may be many other reasons for relaxing the requirements of this section for the drawing figures. It should be noted, though, that when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings.

It is further noted that applicants have previously submitted an amended copy of the sequence listing and the computer readable form of this sequence listing, Paper No. 11, 12/17/1999, but have made no statement regarding whether these "amended" copies of the sequence listing are the same.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 59 and 60 are rejected under 35 U.S.C. § 101 because the claimed invention is directed toward non-statutory subject matter. In the absence of the hand of man, naturally occurring antifungal proteins are considered non-statutory subject matter. *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as "An isolated and purified antifungal protein ...".

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-53, 55, 59 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 51 (52-53 and 55 dependent on) are indefinite in that the recitation "having sufficient identity to the amino acid sequence of SEQ ID NO 15 to retain the antifungal activity of the amino acid sequence of SEQ ID NO 15" is unclear. What is the "sufficient identity" to the amino acid sequence of SEQ ID NO 15 to retain the antifungal activity of the amino acid sequence of SEQ ID NO 15? It appears that applicants are attempting to structurally define the claimed antifungal proteins by functional identity language which is unclear. It is noted that applicants previous amendment, 4/9/2002, "wherein the muteins in subparagraphs (a)-(f) differ from the respective amino acid sequences of which they are muteins only by the replacement, addition or deletion of one amino acid" more clearly defines the structural relationship of the claimed "muteins" relative to the disclosed SEQ ID NOs. In spite of this, the previous recitation, "having sufficient identity to the amino acid sequence of SEQ ID NO 15 to retain the antifungal activity of the amino acid sequence of SEQ ID NO 15" remains unclear and it is suggested that given the above referred to amendment, this recitation be deleted.

Claim 51 (52-53 and 55 dependent on) are indefinite in the recitation "An isolated protein comprising (a) an amino acid sequence encoded by SEQ ID NO 15 and having an antifungal activity..." Based on this recitation it is unclear if a limitation of the

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claimed protein is that it comprises "an amino acid sequence encoded by SEQ ID NO 15 **which** has an antifungal activity" or it comprises "an amino acid sequence encoded by SEQ ID NO 15" **and the protein** has an antifungal activity". The claim is interpreted as if the claimed protein comprises "an amino acid sequence encoded by SEQ ID NO 15 **which** has an antifungal activity", although it is noted that if the claim was interpreted more broadly as in the above second interpretation, art previously made of record could still be used to anticipate this claim. It is suggested that in order to overcome this rejection, applicants amend the claim in each of subparagraphs (a)-(f) such as "an amino acid sequence encoded by SEQ ID NO 15 which has an antifungal activity".

Claims 59 and 60 are indefinite in that they are each drawn to an antifungal protein comprising an amino acid sequence encoded by the open reading frame of SEQ ID NO 15 and 19, respectively. Since "an amino acid sequence" as used in these claims need not have antifungal activity, but rather the protein must have antifungal activity, "an amino acid sequence of the specific SEQ ID NOs" may be as little as two or three amino acid residues. While the claim is not interpreted like this, as discussed above if it was interpreted as the broader interpretation, the art previously made of record would still apply. It is suggested that applicants amend these claims as above or such as "the [an] amino acid sequence encoded by ..." to overcome this rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard Hutson', with a horizontal line extending to the right.

Richard Hutson, Ph.D.
Patent Examiner
Art Unit 1652
October 7, 2002